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DORSEY & WHITNEY LLP
INTELLECTUAL PROPERTY DEPARTMENT
4 EMBARCADERO CENTER
SUITE 3400
SAN FRANCISCO, CA 94111

EXAMINER

FORMAN, BETTY J

ART UNIT PAPER NUMBER

1634

DATE MAILED: 08/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/904,175

Applicant(s)

DOUNG ET AL.

Examiner

BJ Forman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,5-9 and 24-41 is/are pending in the application.
- 4a) Of the above claim(s) 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-3 5-9 24-34 36-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Status of the Claims

1. This action is in response to papers filed 4 June 2004 in which claims 25-26 were amended and claims 36-41 were added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 5 February 2004 under 35 U.S.C. 112, first paragraph are withdrawn in view of the applicant's remarks on page 5 of the response. The previous rejections under 35 U.S.C. 102(e) and 103 are withdrawn in view of the amendments and new grounds for rejection. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 2-3, 5-9, 24-34 and 36-41 are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 2-3, 5-9, 24-34 and 36-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 2-3, 5-9, 24-34 and 36-41 are each indefinite for the recitation “biochip cartridge” because the claims do not define or describe biochip or cartridge components and do not define or describe a relationship between the recited components and a biochip or cartridge.

Claims 2-3, 5, 7-9, 26-31 and 38-41 are indefinite in Claims 26, line 6, for the recitation “said outlet port” because the recitation lacks proper antecedent basis in the claim.

Claims 2-3, 5-9, 35 and 30-41 are indefinite in Claim 6, iii) for the recitation “to minimize the introduction or retention of air bubbles upon introduction of reagents” because the recitation defines functional properties of the outlet port. However, it is unclear how the functional language limits or defines a physical relationship between the inlet and outlet port.

Claim 25 is indefinite for the recitation “said outlet port” because the recitation lacks proper antecedent basis in Claim 24.

Claim 27 is indefinite for the recitation “preferentially allows the escape of gas and retains fluid” because it recites a function or intended use of the membrane. However, it is unclear what structural limitations are being imposed upon the membrane.

Claim 38 is indefinite for the recitation “an assay complex is formed on at least one of said electrodes” because it is a recitation of intended use. However, it is unclear whether the recitation limitations the structures or components of the cartridge.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 24, 2, 5, 7-8, 31 and 36-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Lennox et al (U.S. Patent No. 6,461,490, filed 24 April 1997) as defined by Morris, C. ed (Academy Press Dictionary of Science and Technology, Academic Press, San Diego, 1992, page 1726).

Regarding Claim 24, Lennox et al disclose a biochip cartridge comprising a reaction chamber comprising a substrate comprising a printed circuit board comprising an array of electrodes a self assembled monolayer and a capture binding ligand (Column 14, lines 33-42) and a inlet port for reagent introduction and interconnects for electrical connections (Column 5, lines 12-60; Column 15, lines 12-30; and Fig. 1 and 13-14).

It is noted that the specification defines the claimed circuit board as comprising a substrate coated with a conducting layer and process using photolithography (page 17, lines 27-30). Furthermore, the Academy Press Dictionary defines printed circuit board as "rectangular device onto which various chemical elements and substrates are laid down so that wiring can be applied". Lennox et al disclose the array of electrodes produced via photolithography (Column 14, lines 35-40). Hence, Lennox, disclose the printed circuit board as claimed.

Regarding Claim 2, Lennox et al disclose the biochip wherein the binding ligands comprising nucleic acids (Column 8, lines 59-63).

Regarding Claim 5, Lennox et al disclose the biochip wherein the reaction chamber further comprises an outlet port (Column 5, lines 38-41).

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Regarding Claim 7, Lennox et al disclose the biochip wherein the array is on one surface of the substrate (Column 14, lines 11-14).

Regarding Claim 8, Lennox et al disclose the biochip wherein two surfaces of the substrate comprise an array (Column 14, lines 11-14).

Regarding Claim 31, Lennox et al disclose the biochip wherein the binding ligands comprising proteins (Column 8, lines 59-63).

Regarding Claim 36, Lennox et al disclose the biochip wherein the electrode is on a surface of the printed circuit board (Column 14, lines 35-40 and Fig. 14).

Regarding Claim 37, Lennox et al disclose the biochip wherein the electrode is fabricated on the surface via photolithography (14, lines 35-40 and Fig. 14).

Regarding Claim 38, Lennox et al disclose the biochip comprising an assay complex comprising a binding ligand, target and electron transfer moiety i.e. ionic species (Column 11, lines 55-Column 12, line 35).

Regarding Claim 39, Lennox et al disclose the biochip wherein the monolayer comprises a conductive oligomer (Column 12, lines 13-16).

Regarding Claim 40, Lennox et al disclose the biochip wherein at least one electrode is gold (Column 14, lines 38-39).

Regarding Claim 41, Lennox et al disclose the biochip wherein the monolayer comprise a thiol forming species (Column 2, lines 48-51).

6. Claims 24, 2-3, 5, 7-8, 31, 36-37 and 39-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Ribi et al (U.S. Patent No. 5,491,097, issued 13 February 1996) as

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defined by Morris, C. ed (Academy Press Dictionary of Science and Technology, Academic Press, San Diego, 1992, page 1726).

Regarding Claim 24, Ribí et al disclose a biochip cartridge comprising a reaction chamber comprising a substrate comprising a printed circuit board comprising an array of electrodes a self assembled monolayer and a inlet port for reagent introduction and interconnects for electrical connections (Column 21, line 53-Column 22, line 14; Column 23, lines 12-28; Column 24, lines 36-45) and further comprising a capture binding ligand (Fig. 1-5 #44).

It is noted that the specification defines the claimed circuit board as comprising a substrate coated with a conducting layer and process using photolithography (page 17, lines 27-30). Furthermore, the Academy Press Dictionary defines printed circuit board as "rectangular device onto which various chemical elements and substrates are laid down so that wiring can be applied". Ribí et al disclose the array of electrodes produced via photolithography (Column 10, lines 24-51 and Column 23, lines 12-28). Hence, Ribí et al disclose the printed circuit board as claimed.

Regarding Claim 2, Ribí et al disclose the biochip wherein the binding ligands comprising nucleic acids (Column 7, lines 30-40 and Column 8, lines 29-36).

Regarding Claim 3, Ribí et al disclose the biochip wherein the reaction chamber comprises a gasket for retaining fluids i.e. rubber septum (Column 21, lines 62-67)

Regarding Claim 5, Ribí et al disclose the biochip wherein the reaction chamber further comprises an outlet port (Column 21, lines 65-67).

Regarding Claim 7, Ribí et al disclose the biochip wherein the array is on one surface of the substrate (Column 22, lines 1-14).

Regarding Claim 8, Ribí et al disclose the biochip wherein two surfaces of the substrate comprises an array (Column 22, lines 1-14).

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Regarding Claim 31, Ribí et al disclose the biochip wherein the binding ligands comprising proteins (Column 7, lines 30-40 and Column 8, lines 10-28).

Regarding Claim 36, Ribí et al disclose the biochip wherein the electrode is on a surface of the printed circuit board (Column 10, lines 24-51).

Regarding Claim 37, Ribí et al disclose the biochip wherein the electrode is fabricated on the surface via photolithography (Column 23, lines 14-16).

Regarding Claim 39, Ribí et al disclose the biochip wherein the monolayer comprises a conductive oligomer (Column 3, lines 15-40 and Column 4, lines 13-29).

Regarding Claim 40, Ribí et al disclose the biochip wherein at least one electrode is gold (Column 10, lines 24-26).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 6, 2-3, 5, 7-9, 24xd-33 and 36-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox et al (U.S. Patent No. 6,461,490, filed 24 April 1997) as defined by Morris, C. ed (Academy Press Dictionary of Science and Technology, Academic Press, San Diego, 1992, page 1726) and Anderson et al (U.S. Patent No. 6,326,211, filed 19 April 1999).

Regarding Claims 6, 24 and 26, Lennox et al disclose a biochip cartridge comprising a reaction chamber comprising a substrate comprising an array of electrodes a self assembled monolayer and a capture binding ligand (Column 14, lines 33-42) and a inlet port and an

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outlet port (Column 5, lines 37-41) and interconnects for electrical connections (Column 5, lines 12-60; Column 15, lines 12-30; and Fig. 1 and 13-14).

Lennox et al further teach the cartridge comprises inlet port and outlet port i.e. vent are provided to facilitate fluid flow through the chamber (Column 5, lines 38-41 and Column 11, lines 31-34) but they are silent regarding positioning of the inlet port and vent. Anderson teaches a similar cartridge comprising a biochip array, the cartridge comprising an inlet port (#110) and vent comprising a membrane filter (#118) (Column 20, lines 56-62 and Column 22, lines 6-28) wherein the inlet is positioned at the bottom of the chamber and the vent is positioned at the top of the chamber. Anderson et al further teach the arrangement of the outlet and vent facilitates selective movement of reagents within the chamber, permits gas within the chamber to be expelled upon reagent introduction (Column 30, lines 30-67) and allows reagent mixing by letting bubbles within the chamber to exit upon reagent introduction (Column 3, lines 50-56).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the inlet and vent in the reaction chambers of Lennox et al by positioning the inlet at the bottom of the chamber and the vent at the top of the chamber as taught by Anderson et al. One of ordinary skill in the art would have been motivated to do so by the teaching of Anderson et al wherein they teach the arrangement facilitates selective movement of reagents within the chamber, permits gas within the chamber to be expelled upon reagent introduction (Column 30, lines 30-67) and allows reagent mixing by letting bubbles within the chamber to exit upon reagent introduction (Column 3, lines 50-56).

Regarding Claim 2, Lennox et al disclose the biochip wherein the binding ligands comprising nucleic acids (Column 8, lines 59-63).

Regarding Claim 3, Lennox et al teach the chamber is designed to hold a solution (Column 1, lines 29-30) but they are silent regarding the presence of a gasket. However, Anderson et al teach the similar chamber for holding a solution wherein the chamber

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comprises a gasket (i.e. diaphragm) that retains fluid in contact with the array (Column 21, lines 35-60). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the diaphragm of Anderson et al to the chamber of Lennox et al for the expected benefit of sealing the reaction chamber as preferred by Anderson (Column 4, line 16-20 and Column 36, lines 53-55).

Regarding Claim 5, Lennox et al disclose the biochip wherein the reaction chamber further comprises an outlet port (Column 5, lines 38-41).

Regarding Claim 7, Lennox et al disclose the biochip wherein the array is on one surface of the substrate (Column 14, lines 11-14).

Regarding Claim 8, Lennox et al disclose the biochip wherein two surfaces of the substrate comprises an array (Column 14, lines 11-14).

Regarding Claim 9, Anderson et al teach the similar cartridge further comprising means a top (Column 16, lines 2-11) and at least one storage well comprising assay reagents (Column 24, lines 44-65 and Fig. 5 A & B) wherein the arrangement of storage wells adjacent to the substrate provides easy access to reagents and convenient storage reagents (Column 25, lines 42-52). While they do not specifically teach the cap comprises the storage well, they clearly suggest such a configuration when they teach adjacent to and easy access. Furthermore, the courts have stated that a rearrangement of parts known in the art is a mere design choice and not patentable over the prior art parts. Therefore, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the arrangement of cap and storage well to incorporate the storage well in the cap based on the desired adjacent arrangement providing convenient storage taught by Anderson et al (Column 25, lines 42-52).

In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) (Claims to a hydraulic power press which read on the prior art except with regard to the position of the starting switch were held unpatentable because shifting the position of the starting switch would not have modified the operation of the device.); In re Kuhle, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) (the particular placement of a contact in a conductivity measuring device was held to be an obvious matter of design choice) (MPEP 2144.04).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the cap comprising a storage well as taught by Anderson et al to the cartridge of Lennox et al for the expected benefits of easy access to reagents and convenient storage reagents as taught by Anderson et al (Column 25, lines 42-52).

Regarding Claims 25 and 27, Lennox et al disclose the biochip of Claim 24 comprising an outlet port (Column 11, lines 31-34) but are silent regarding a membrane filter. However, Anderson et al teach the similar chamber wherein the outlet port comprises a semi permeable membrane whereby gas is permitted to escape while maintaining fluid within the chamber (Column 22, lines 6-28). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the outlet vent of Lennox et al by addition of a semi permeable membrane as taught by Anderson et al for the expected benefit of allowing gas escape while maintaining the fluid (Column 22, lines 6-28).

Regarding Claim 28, Anderson et al teach the preferred semi permeable membrane comprises polytetrafluorethylene i.e. TEFLON (Column 22, lines 14).

Regarding Claim 29, Anderson et al further teach the membrane allows escape of gas while retaining the sample fluid e.g. Teflon (Column 22, lines 6-17 and Fig. 2B) but they do not teach the permeable membrane is Gortex™. However, the specification teaches that Teflon and Gortex™ are functional equivalents (page 13, second paragraph).

For example, a semi-permeable membrane or filter may be used, that preferentially allows the escape of gas but retains the sample fluid in the chamber. For example, porous teflons such as Gortex™ allow air but not fluids to penetrate.

The courts have stated with regard to homologs that the greater the physical and chemical similarities between the claimed species and any species disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner (see *Dillon*, 99 F.2d at 696, 16 USPQ2d at 1904). Therefore, based on the functional equivalency of Teflon and Gortex™ one of ordinary skill in the art would have been motivated to

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substitute Gortex™ for the Teflon of Anderson et al because one of ordinary skill would have expected the two membranes to function in an equivalent manner.

Regarding Claim 30, Lennox et al teach a printed circuit board. It is noted that the specification defines the claimed circuit board as comprising a substrate coated with a conducting layer and process using photolithography (page 17, lines 27-30). Furthermore, the Academy Press Dictionary defines printed circuit board as “rectangular device onto which various chemical elements and substrates are laid down so that wiring can be applied”. Lennox et al disclose the array of electrodes produced via photolithography (Column 14, lines 35-40). Hence, Lennox, disclose the printed circuit board as claimed.

Regarding Claim 31, Lennox et al disclose the biochip wherein the binding ligands comprising proteins (Column 8, lines 59-63).

Regarding Claims 32 and 33, Lennox et al disclose the chamber comprises an inlet port and vent (Column 11, lines 31-34) but are silent regarding the physical relationship of the port and vent.

Anderson teaches a similar cartridge comprising an inlet port (#110) and vent (#118) (Column 20, lines 56-62 and Column 22, lines 6-28) wherein the inlet and vent are separated by fluidically connected. Anderson et al further teach the arrangement of the outlet and vent facilitates selective movement of reagents within the chamber, permits gas within the chamber to be expelled upon reagent introduction (Column 30, lines 30-67) and allows reagent mixing by letting bubbles within the chamber to exit upon reagent introduction (Column 3, lines 50-56).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the inlet and vent in the reaction chambers of Lennox et al by positioning the inlet at the bottom of the chamber and the vent at the top of the chamber as taught by Anderson et al. One of ordinary skill in the art would have been motivated to do so by the teaching of Anderson et al wherein they teach the arrangement facilitates selective movement of reagents within the chamber, permits gas within the chamber to be expelled upon

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reagent introduction (Column 30, lines 30-67) and allows reagent mixing by letting bubbles within the chamber to exit upon reagent introduction (Column 3, lines 50-56).

Regarding Claim 36, Lennox et al disclose the biochip wherein the electrode is on a surface of the printed circuit board (Column 14, lines 35-40 and Fig. 14).

Regarding Claim 37, Lennox et al disclose the biochip wherein the electrode is fabricated on the surface via photolithography (14, lines 35-40 and Fig. 14).

Regarding Claim 38, Lennox et al disclose the biochip comprising an assay complex comprising a binding ligand, target and electron transfer moiety i.e. ionic species (Column 11, lines 55-Column 12, line 35).

Regarding Claim 39, Lennox et al disclose the biochip wherein the monolayer comprises a conductive oligomer (Column 12, lines 13-16).

Regarding Claim 40, Lennox et al disclose the biochip wherein at least one electrode is gold (Column 14, lines 38-39).

Regarding Claim 41, Lennox et al disclose the biochip wherein the monolayer comprise a thiol forming species (Column 2, lines 48-51).

9. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox et al (U.S. Patent No. 6,461,490, filed 24 April 1997) as defined by Morris, C. ed (Academy Press Dictionary of Science and Technology, Academic Press, San Diego, 1992, page 1726) and Anderson et al (U.S. Patent No. 6,326,211, filed 19 April 1999) as applied to Claim 9 above and further in view of Hayes et al (U.S. Patent No. 6,334,980, filed 25 September 1998).

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Regarding Claim 34, Lennox et al describe the components of the cartridge (Column 1, lines 12-63 and Column 14, line 28-Column 15, line 31) but do not specifically teach the top is removable.

However, reaction chambers having removable covers were well known in the art at the time the claimed invention was made as taught by Hayes et al who specifically teach the removable cover permits addition of reagents to the chamber at desired times e.g. later (Column 12, lines 44-49). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the reaction chamber of Lennox et al by providing a removable cover as taught by Hayes et al for the expected benefit of permitting reagent addition as desired (Column 12, lines 44-49).

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

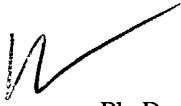
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
August 16, 2004